

VZCZCXRO8416  
RR RUEHHM RUEHLN RUEHMA RUEHPB  
DE RUEHHI #1450/01 1651014  
ZNR UUUUU ZZH  
R 141014Z JUN 06  
FM AMEMBASSY HANOI  
TO RUEHC/SECSTATE WASHDC 2360  
INFO RUEHHM/AMCONSUL HO CHI MINH CITY 1352  
RUEHZN/ENVIRONMENT SCIENCE AND TECHNOLOGY COLLECTIVE  
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RUEAUSA/DEPT OF HHS WASHDC  
RUEKJCS/SECDEF WASHDC

UNCLAS SECTION 01 OF 05 HANOI 001450

SIPDIS

STATE FOR O/GAC, EAP/MLS, EAP/EP, INR, OES/STC, AND OES/IHA  
STATE PASS TO USAID FOR ANE AND GH (DCARROLL, SCLEMENTS AND  
PCHAPLIN)  
STATE PASS TO HHS/OGHA (WSTIEGER, EELVANDER AND ABHAT)  
BANGKOK FOR USAID (TBEANS, LBRADSHAW AND BSLATER)

SIPDIS

E.O. 12958: N/A  
TAGS: [TBIO](#) [KHIV](#) [EAID](#) [SOCI](#) [TBIO](#) [VM](#)  
SUBJECT: THE ROLE OF ANTIRETROVIRAL THERAPY IN VIETNAM'S  
FIGHT AGAINST HIV/AIDS

HANOI 00001450 001.2 OF 005

¶1. (U) Summary. Although the estimated prevalence of HIV/AIDS in Vietnam is relatively low compared to most Southeast Asian countries, it has continued to rise in each of the past five years, increasing by 25 percent from 2004 to 2005. The estimated national HIV prevalence rate is 0.44 percent, or approximately 215,000 HIV-infected persons. It appears that the epidemic is spreading outside the most-at-risk populations to infect clients of sex workers, spouses of clients and intravenous drug users, and to their children. A key element of any comprehensive treatment of HIV-infected individuals is appropriate antiretroviral therapy (ART). The availability of quality ART in Vietnam is limited and the estimated number of people receiving ART is low due to lack of capacity. Since August 2005, the President's Emergency Plan for AIDS Relief (PEPFAR) Vietnam program has provided the majority of high-quality ART in Vietnam in the form of imported brand-name ARVs with FDA tentative approval. In January 2006, the MOH agreed to allow PEPFAR to procure and import FDA tentatively approved generic ARVs. Consequently, the PEPFAR Vietnam program is procuring increasing numbers of imported generic ARV medications. Sustainability of ARV treatment programs is of critical concern. Unless Vietnam obtains Round 6 Global Fund funding, or the Government of Vietnam (GVN) or other donor is able to procure additional ARVs, PEPFAR will continue to be the main supplier of ARVs for the next several years. End Summary.

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The President's Emergency Plan for AIDS Relief  
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¶2. (U) President Bush's Emergency Plan for AIDS Relief (PEPFAR) is a five-year USD 15 billion plan to provide prevention, care and treatment programs for People Living with HIV/AIDS (PLWH) and to prevent new cases. In 2004, Vietnam became the 15th focus country to join the Emergency Plan and the only focus country in Asia. In FY2006, the United States will provide approximately USD 34 million to support Vietnam's fight against HIV/AIDS.

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The HIV/AIDS Epidemic in Vietnam  
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¶3. (U) Of Vietnam's 83 million inhabitants, approximately 57 percent are less than 30 years old. The majority of HIV positives in Vietnam occur among young males ages 20-29 (greater than 1 percent prevalence). Based on GVN data, the national HIV prevalence rate is 0.44 percent, or approximately 215,000 HIV-infected persons. Although the estimated prevalence of HIV/AIDS in Vietnam is relatively low compared to most Southeast Asian countries, it has continued to rise in each of the past five years, increasing by 25 percent from 2004 to 2005. The HIV epidemic in Vietnam has been primarily driven by intravenous drug users (IDUs) and commercial sex workers (CSW) and concentrated in population segments traditionally thought to be at high risk.

¶4. (U) According to UNAIDS Country Coordinator Nancy Fee, there is great concern that the epidemic appears to be spreading outside the most-at-risk populations to infect clients of sex workers, and spouses of clients and IDUs, and to their children. In addition, given the prevalence is rising in women not normally associated with the most-at-risk groups, UNAIDS and the Ministry of Health (MOH) attribute an increasing proportion of HIV transmission to sexual transmission. Although HIV/AIDS has been detected in each of Vietnam's 64 provinces, the highest rates of prevalence have been recorded in Haiphong, Vung Tau, Ho Chi Minh City (HCMC), and Quang Ninh Province.

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Antiretroviral Therapies: Opening the Door to Treatment  
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¶5. (U) A key element of the PEPFAR program in Vietnam is the comprehensive treatment of HIV-infected individuals using appropriate ART. (NOTE: Antiretroviral therapy (ART) is the program delivering antiretroviral drugs (ARV).  
ENDNOTE) The PEPFAR country operational plan for Vietnam

HANOI 00001450 002.2 OF 005

establishes a target of treat 22,000 ART-eligible individuals by 2008. In Vietnam, an estimated 35,000 HIV-infected individuals are eligible for ART.

¶6. (U) The Vietnam PEPFAR program is initially focusing comprehensive ART activities in six high-prevalence PEPFAR "focus" provinces and cities: Haiphong, Hanoi and Quang Ninh in the north and Ho Chi Minh City, Can Tho and An Giang in the south. In these provinces, approximately 14,500 persons are eligible for treatment with ARVs. Eligibility for ARV treatment is based on established clinical criteria from WHO recommendations and agreed upon by members of the PEPFAR Vietnam and MOH team.

¶7. (U) The availability of quality ART in Vietnam is limited, as is competent supervision of care. Although MOH guidelines for ART exist, domestically produced and imported, generic ARV medications are freely prescribed by untrained physicians and are readily available directly to customers by local pharmacies with few controls. As a result, some PLWAs are exposed to inadequate treatments, including mono- and dual-therapy (one or two-drug regimens), instead of the standard three-drug regimen, thereby reducing quality of care and increasing the risk of developing drug-resistant HIV strains.

¶8. (U) Since August 2005, the PEPFAR Vietnam program has provided the majority of high-quality ART in Vietnam, in the form of imported branded and FDA tentatively approved ARVs. Over 1,500 adults and children have initiated ARV therapy at 21 PEPFAR-supported outpatient clinics. Eleven sites in four focus provinces are providing services for Prevention of Mother to Child Transmission (PMTCT) and ARVs to prevent transmission has been provided to over 400 HIV-positive mothers and infants.

¶9. (U) In January 2006, the MOH agreed to allow PEPFAR to procure and import FDA tentatively approved generic ARVs. (NOTE: Vietnam is only the fourth of 15 focus countries to approve this. ENDNOTE) Consequently, the PEPFAR Vietnam program is now procuring increasing numbers of imported generic ARV medications with FDA tentative approval. To date, no ARVs produced in Vietnam have received FDA tentative approval or WHO pre-qualification, although the MOH Drug Administration has indicated that they are applying for the latter.

¶10. (U) Other, non-PEPFAR programs also provide ART in Vietnam. These include the MOH, the Global Fund for HIV/AIDS, Tuberculosis and Malaria (GFATM), and ESTHER, which is a project sponsored by the Government of France. These programs procure ARVs for distribution, but management of drug distribution and oversight over care and treatment programs is variable. ESTHER provides ART to approximately 400 patients. However, they plan to phase-out purchase and provision of ARVs as additional sources of reliable ARVs become more readily available.

¶11. (U) The MOH distributed to treatment facilities in 64 provinces ARVs for 3,000 persons. However, the capacity of provincial facilities to delivery ART is fairly limited. The MOH reports that ARVs have not yet been distributed to patients due to lack of adequate clinical training and oversight. As the MOH is the principal recipient for the GFATM, capacity to adequately supervise GFATM-supported ART also suffers from the same limitations in care and treatment. During 2006, GFATM-Vietnam will procure ARV to treat approximately 2000 persons, yet as of the end of April 2006, only 300 patients receive ARV through GFATM procurement.

¶12. (U) Since the end of 2005, PEPFAR Vietnam program has been working closely with GFATM and MOH representatives to coordinate ARV distribution and management and to provide PEPFAR assistance to GFATM ART in the form of clinical/laboratory support and clinical technical assistance. In addition to closer donor coordination, which ensures that the ARVs are getting to the right people, the PEPFAR Vietnam program actively pressed the GVN to allow the importation of generic ARV medications with FDA tentative approval, which allows limited resources to support more people.

HANOI 00001450 003.2 OF 005

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PEPFAR's Strategy for Achieving ART Targets  
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¶13. (U) To achieve the target of treating 22,000 ART-eligible individuals by 2008, the PEPFAR Vietnam strategy applies a four-tiered program of activities. First, PEPFAR-procured ARVs will be provided to eligible individuals at 36 sites in the six focus provinces. The services to be offered include initiation and scale up of adult, pediatric and PMTCT ART with comprehensive services including ARV, laboratory services, training, adherence and patient readiness training, and linkages to comprehensive prevention and care services.

¶14. (U) Second, PEPFAR Vietnam will strengthen coordination with MOH and GFATM to support ART provided from these sources in existing USG-supported outpatient clinics through training, technical assistance and patient laboratory monitoring. Third, PEPFAR Vietnam supports the improvement of national reference laboratories including external quality assurance, and provincial laboratory capacity.

¶15. (U) Finally, PEPFAR Vietnam will provide leadership to strengthen national capacity-building initiatives including support of national training strategies, national ARV implementation guidelines, quality assurance programs,

monitoring and evaluation, and development of an MOH Drug Management Information System Task Force to coordinate drug procurement and supply mechanisms throughout Vietnam. In the near future, PEPFAR Vietnam will begin using the PEPFAR-developed Supply Chain Management System (SCMS) to procure ARVs.

¶16. (U) In FY05, PEPFAR Vietnam supported the MOH to develop a national ARV protocol and training strategy and to establish an ARV site readiness assessment protocol for GFATM sites. This protocol is designed to help the MOH determine if clinics are capable to receive and manage ARVs, to prescribe the appropriate ARVs, to monitor ARV effectiveness and manage follow-up care. PEPFAR Vietnam collaborated with other agencies including WHO to develop and distribute national guidelines for treatment of opportunistic infections with ARV and supported training for over 150 physicians, nurses, counselors and pharmacists to begin ARV for adults and children.

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An Action Plan for FY06: Scaling Up ARV Treatment  
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¶17. (U) With USG-funded ARVs, PEPFAR Vietnam will continue to put more patients on ARVs in the 26 existing clinics and five new clinics that will start prescribing ARVs by the end of 2006. The PEPFAR Vietnam team expects to meet and perhaps even exceed the FY06 target of 1,900 patients by September, 2006.

¶18. (U) Scale-up will be achieved according to the strategy outlined above. As previously noted, the GFATM and the MOH procure ARVs through other funding mechanisms. In a continued partnership and under the leadership of the MOH, PEPFAR Vietnam supported the development of a National ARV treatment implementation and readiness protocol and the National Care and Treatment Plan of Action. The National ARV treatment protocol is based on protocols developed for PEPFAR Vietnam-supported ARV clinics. The MOH requested assistance from PEPFAR Vietnam to support training and technical assistance in the provinces where the MOH will be supporting ARV treatment through drugs procured by GFATM and MOH. PEPFAR Vietnam is currently working with the MOH to develop a national training curriculum and plans for follow up training and technical assistance to sites outside of the six focus provinces/cities. ARV lab monitoring services in some sites where GFATM and MOH provide treatment services is also underway.

¶19. (U) Additionally, PEPFAR Vietnam is developing an innovative pilot program in HCMC to support transition residents moving from drug rehabilitation centers ("06 Centers") to community-based clinics that will support them

HANOI 00001450 004.2 OF 005

with counseling, relapse prevention, care and treatment services. If successful, the pilot will serve as a model for expanding treatment services in this large population of marginalized patients. PEPFAR Vietnam will also expand capacity of USG partners in Vietnam by providing technical assistance for all PEPFAR Vietnam sites as requested; providing technical assistance to sites jointly supported by USG and GFATM; strengthening Vietnamese clinical training teams; and, developing an on-call system to provide HIV expertise by phone and email back up to clinics in more remote areas.

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Critical Challenges and Paths to Expand ARV Treatment  
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¶20. (U) The PEPFAR Vietnam program faces a number of challenges as it supports the GVN and its partners to provide quality ARV treatment and care. Among these challenges is the lack of transparency by the MOH, which

limits the extent to which resources can be collaboratively used. To address this challenge, the PEPFAR Vietnam program will assist the MOH to maximize resources and provide treatment that meets international standards of care across MOH clinics. PEPFAR Vietnam, in collaboration with other donors and international organizations, will also encourage MOH to coordinate ARV procurement, distribution and care. In addition, PEPFAR Vietnam will continue to meet regularly with representatives of MOH and GFATM to encourage greater collaboration in programming.

¶21. (U) Care and treatment services must be accessible, despite the increasing number of patients served and the increasing number of clinics providing ARVs. Accessibility is particularly challenging for marginalized populations such as IDUs and CSWs. With an estimated 160,000 registered IDUs, of whom approximately 30-50 percent are HIV-positive and approximately 40,000 reside in rehabilitation centers, the establishment of comprehensive treatment programs requires a systematic, coordinated program that ensures continuity of care as many of the center residents are released into the community. To address this challenge, PEPFAR Vietnam will explore ways to support effective programs that reach the most patients in need of treatment including more marginalized populations and hidden groups that may not be accessing via current care services. PEPFAR Vietnam will assist programs funded by the World Bank and GFATM that provide ARVs to patients living in the rehabilitation centers.

¶22. (U) In settings where ongoing intravenous drug use may complicate ARV treatment and methadone will not be immediately available, a continued focus needs to be placed on quality, adherence support, and good treatment readiness preparation for patients. Using evidence-based results, PEPFAR Vietnam will assess adherence to ARV regimens and program loss to follow-up and explore ways to improve these indicators based on data. PEPFAR Vietnam, in collaboration with other donors and international agencies, will continue to encourage the MOH to allow implementation and rapid scale-up of medication-assisted therapy (i.e., methadone and other medications) as an important adjunct to successful ARV programming.

¶23. (U) Another challenge is the lack of an established national-level drug management and patient monitoring system. Through the World Health Organization (WHO), PEPFAR Vietnam supports the formation of a centralized procurement and distribution system for all Vietnam programs and is developing an in-house drug management system based on established principles tailored to Vietnam's needs.

¶24. (U) Sustainability of ARV treatment programs is of critical concern. Unless Vietnam obtains Round 6 GFATM funding, or the GVN or another donor is able to procure additional ARVs, PEPFAR Vietnam may continue to be the main supplier of ARVs and drugs for opportunistic infections for the next several years. The GVN has requested PEPFAR Vietnam to assist with their Round 6 application to the GFATM. PEPFAR Vietnam will assist MOH in this effort where appropriate. The MOH decision on January 2006 to allow the procurement and importation of FDA tentatively approved

HANOI 00001450 005 OF 005

generic ARVs will ensure that limited resources reach a greater number of patients. PEPFAR Vietnam has also offered assistance to MOH's Drug Administration to provide support for domestically produced ARVs to receive tentative approval from FDA. However, the MOH has decided to delay their application to FDA and apply for WHO prequalification, citing stringent requirements by FDA.

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The Cost of ART  
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¶25. (U) Currently, the cost of the first-line regimen is approximately USD 350 per year and is estimated to fall to as low as USD 320. This is comparable to regimens procured through other donors such as the GFATM and the Clinton Foundation. This has been achieved through the importation of some FDA tentatively improved drugs, which have both lowered the overall costs and improved the rapidity of drug delivery. Vietnam has experience delays in delivery of up to nine months for some branded ARVs. Currently, PEPFAR is the only donor procuring second-line ARVs, which is estimated to account for seven percent of the purchased drugs in 2006. The Clinton Foundation will be procuring some second line drugs for children for 2007. The current cost of the standard second line adult regimen is just over USD 3,000 per patient per year.

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Summary  
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¶26. (U) The lack of sufficient quality and quantity of ARV to treat Vietnam's HIV/AIDS patients continues to be troubling. Although Vietnam is receiving considerable financial and technical assistance from the international donor community, the introduction of ARV treatment programs requires infrastructure development, including physical plants and personnel, at the many levels of Vietnam's vast health care system administered by the MOH. Domestic production of low-cost ARVs meeting international standards of quality does not appear to be coming soon, although the GVN decided to allow the importation of ARVs with tentative FDA approval or WHO prequalification. Sustainability of funding for sufficient quantities of ARV may be in jeopardy if Vietnam does not contend well in Round 6 of the GFTAM. Developing a sustainable funding stream for ART and prevention programs is critical to the ability of the GVN to control a growing public health problem, and to ensure the long-term success of PEPFAR Vietnam's initial achievements in expanding ARV treatment to those in need.

Boardman